UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AETNA, INC.,	)	
	)	
Plaintiff,	)	Civil Action No.
	)	04 CV 10958 (PBS)
	)	
v.	)	
	)	
PFIZER INC. and WARNER-LAMBERT COMPANY,	)	
	)	
Defendants.	)	

FIRST AMENDED COMPLAINT WITH JURY DEMAND

Aetna, Inc. ("Aetna" or "Plaintiff"), by its undersigned counsel, alleges, upon personal knowledge as to itself and its own acts and upon information and belief (based on the investigation of counsel) as to all other matters as follows:

I. SUMMARY OF THE CLAIMS

1. Aetna brings this lawsuit against Defendant Pfizer Inc. ("Pfizer") and its wholly owned subsidiary, Defendant Warner-Lambert Company ("Warner-Lambert") (collectively, "Defendants"). Pfizer currently markets and sells the drug Neurontin, which has been approved for the treatment of epilepsy. Prior to Pfizer's acquisition of Warner-Lambert in 2000, Neurontin was marketed and sold by Parke-Davis, a division of Warner-Lambert.

2. Commencing in or about 1995, Parke-Davis created and implemented a deceptive marketing and sales scheme in order to substantially increase the sales of Neurontin ("Neurontin"), a drug that reportedly earned Defendants more than $2.7 billion in worldwide

sales in 2003, and reap unlawful profits at the expense of healthcare insurers. Defendants systematically engaged in deceptive sales and marketing practices which caused individual patients and their insurers to pay for Neurontin to treat a variety of illnesses and symptoms for which Neurontin had not received approval from the United States Food and Drug Administration (the "FDA"), and for which the drug was not safe or medically efficacious. Defendants knew there was no scientific basis to support such "off-label" uses. Defendants' deceptive conduct targeted health insurers, patients and others, with the purpose of increasing the market for Neurontin and Defendants' profits, at the expense of Plaintiff.

3. Defendants' deceptive marketing and sales practices included: (a) directly soliciting physicians to prescribe Neurontin for a variety of uses not approved by the FDA, called "off-label" uses; (b) misrepresenting the safety and medical efficacy of Neurontin for off-label uses; (c) misrepresenting the existence and findings of scientific data, studies, reports and clinical trials concerning the safety and medical efficacy of Neurontin for a variety of off-label uses; (d) misrepresenting the credentials and qualifications of certain of Defendants' employees as specialists, medical researchers, physicians and scientific employees in order to market and sell Neurontin for various off-label uses; (e) improperly compensating physicians for prescribing Neurontin for off-label uses; (f) instructing and coaching doctors and pharmacists how to conceal and misrepresent the use of Neurontin for off-label uses on claim forms submitted to Plaintiff; (g) causing doctors and pharmacists to submit claim forms to Plaintiff containing misinformation regarding Neurontin; and (h) causing the publication of articles, studies and reports misrepresenting the scientific credibility of data and the medical efficacy of Neurontin for off-label uses.

4. Defendants' wrongful conduct caused Plaintiff to pay for claims for Neurontin to treat a variety of off-label conditions when Neurontin was not safe or medically effective for the treatment of such conditions. As a result, Defendants substantially increased their sales of Neurontin based on misrepresentations, concealment and false scientific data.

5. In 1996, 50% of Neurontin's sales were attributable to off-label uses. By 2000, as a result of the success of Defendants' deceptive practices, more than 78% of the Neurontin prescriptions written were for off-label uses. Sales of the drug continue to grow at a rate of 50% per year, fueled primarily by off-label uses.

II. JURISDICTION AND VENUE

6. This Court has jurisdiction pursuant to 28 U.S.C. §1332(a) and (c) (diversity jurisdiction). There is complete diversity of citizenship between Plaintiff and Defendants. Plaintiff's damages exceed $75,000, exclusive of interest and costs.

7. Venue is proper in this jurisdiction under 28 U.S.C. § 1391(a). Each of the Defendants is subject to personal jurisdiction in this District and a substantial part of the events giving rise to Plaintiff's claims occurred in this District.

III. PARTIES

8. Aetna is a Pennsylvania corporation that maintains its principal place of business in Hartford, Connecticut. Aetna and its subsidiaries are managed care organizations which provide health payment benefits to more than 13 million people in virtually every state and territory of the United States and have agreements with tens of thousands of participating pharmacies in the United States. Between 1996 and 2003, Aetna paid tens of millions of dollars

to U.S. pharmacies for prescriptions of Neurontin for Aetna members in the United States, the District of Columbia and the Commonwealth of Puerto Rico.

9. Defendant Pfizer is a Delaware corporation that maintains its principal place of business at 235 East 42nd Street, New York, New York. Pfizer is principally engaged in the manufacture and sale of pharmaceuticals and is one of the largest pharmaceutical companies in the United States, whether measured by number of prescriptions written, revenues or market capitalization.

10. Defendant Warner-Lambert, including its Parke-Davis division, was acquired by Pfizer in June 2000. Prior to the acquisition, Warner-Lambert was a Delaware corporation that maintained its principal place of business at 201 Gabor Road, Morris Plains, New Jersey. In 1993, Warner-Lambert received FDA approval to market Neurontin in the United States and did so through its Parke-Davis division. Warner-Lambert is presently a wholly owned subsidiary of Pfizer.

IV. NEURONTIN

11. Under applicable statutes and regulations, the manufacturer of a prescription drug regulated by the FDA may not promote or market the use of the drug for purposes or in dosages other than those approved by the FDA. The use or uses and dosages approved by the FDA are set forth in the drug's labeling, the content of which is also approved by the FDA.

12. Pharmaceutical companies spend billions of dollars each year trying to persuade doctors to prescribe their drugs. Although it is not unlawful for physicians to prescribe approved drugs for uses or at dosages different than those set forth in a drug's labeling, the Food Drug and Cosmetic Act (the "FDCA") contains strict regulations governing the drug companies' promotion

of such off-label use. This regulatory scheme is meant to ensure that pharmaceutical companies provide doctors and patients with trustworthy information so that medications are prescribed appropriately.

13. An amendment to the FDCA, The Food and Drug Administration Act of 1997 (the "FDAMA"), 21 U.S.C. § 360aaa *et seq.*, allows a manufacturer to disseminate "written information concerning the safety, effectiveness, or benefit of a use not described in the approved labeling of a drug" if the manufacturer submits an application to the FDA seeking approval of the drug for the off-label use, the materials are unabridged peer-reviewed articles or qualified referenced publications and are provided to the FDA prior to dissemination, and the materials to be disseminated include disclosures that the information pertains to an unapproved use of the drug. 21 U.S.C. §360aaa(a).

14. Neurontin was approved by the FDA in 1993 for use as an "adjunctive therapy" for epilepsy in doses from 900 to 1800 milligrams per day. Adjunctive therapy means that the drug was approved as an add-on drug in the event that a primary anti-epilepsy drug was not successful. Although Parke-Davis had previously filed four different patent applications for Neurontin, claiming it to be effective in the treatment of depression, neurogenerative disease, mania and bipolar disease and for anxiety and panic, Defendants never sought FDA approval for the use of Neurontin to treat these conditions.

15. There are two million persons who suffer from epilepsy in the United States, a relatively small market for a major pharmaceutical company. In addition, Parke-Davis' original patent on Neurontin was set to expire in December 1998, leaving Parke-Davis with only a small window of exclusivity for this drug. After the expiration of the Neurontin patent, Defendants

would be forced to share the market for Neurontin with generic drug manufacturers, substantially reducing Defendants' profits and their ability to keep Neurontin's retail price at a monopolistic level.

16. In or about 1995, Parke-Davis embarked on a scheme to broaden the market for Neurontin and began illegally promoting Neurontin to physicians for at least eleven off-label uses, including pain management, psychiatric disorders, anxiety and depression. Although Neurontin had not received FDA approval for the treatment of these conditions, Parke-Davis recognized the potential to obtain enormous profits from the promotion of Neurontin for other diseases and at higher dosages than those approved by the FDA.

V. DEFENDANTS' DECEPTIVE CONDUCT

17. Executives at Parke-Davis decided to avoid the FDAMA regulatory process as required for the marketing of a new use of a drug and to proceed in a deceptive fashion in order to expand the lucrative off-label market for Neurontin. The decision was also made to conceal the deceptive means which would be used to market the drug.

18. As more fully explained below, Defendants designed and employed a variety of deceptive practices to communicate false information to physicians regarding the safety and medical efficacy of Neurontin, to pay physicians for prescribing the drug, and to mislead third-party payers regarding the usage of Neurontin, all in an effort to increase sales of Neurontin.

19. Although federal regulations prohibit Defendants from promoting Neurontin for non-approved FDA uses, the regulations permit a drug manufacturer to distribute publications created by independent third parties that described results of off-label uses of its drug, provided

such materials were only distributed in response to non-solicited requests from physicians. Defendants devised a marketing strategy that deceptively tried to make it appear that they were taking advantage of this narrow exception. To this end, Parke-Davis bypassed its regular sales force and instead used "medical liaisons" to market Neurontin to physicians and to distribute directly to physicians medical literature created by Parke-Davis.

20. Parke-Davis also surreptitiously hired non-physician technical writers to write articles for medical journals, which Parke-Davis employees reviewed and approved, and then paid physicians for the right to use their names as the articles' "authors." Parke-Davis then retained outside firms to broker these articles to various medical journals in order to make it appear that Parke-Davis did not create and sponsor the articles themselves.

21. To reward physicians for prescribing or advocating Neurontin, Parke-Davis made substantial payments to physicians under the guise of "consultant" arrangements, medical education seminars, grants, and "studies," that required virtually nothing from the physicians. To ensure that third-party global payers covered claims for Neurontin, Parke-Davis employees instructed and assisted pharmacists and others to misrepresent the use of Neurontin in claims submitted to such third-party payers.

A. Defendants' Use of "Medical" Liaisons to Promote Off-Label Neurontin Prescriptions

22. A principle component of Defendants' deceptive scheme was the hiring and deployment of approximately 60 "medical liaisons," whose real function was to solicit physicians actively to promote off-label uses of Neurontin, using cash payments as a reward and incentive. This off-label solicitation was done in a covert fashion, largely in private meetings with doctors.

23. In the pharmaceutical industry, medical liaisons are supposed to be individuals with scientific training who do not function as salespersons, but rather as persons who are available at a physician's request to provide balanced scientific information about a company's products. However, at Parke-Davis, many of the persons given the title "medical liaisons" were hired from the sales department and were compensated, at least in part, on the basis of sales. These medical liaisons had no discernable scientific or medical functions and had no communication or interaction with Parke-Davis' actual medical research divisions.

24. Because federal regulations prohibited the normal marketing force from delivering the off-label message, Parke-Davis increasingly hired medical liaisons and trained them to aggressively solicit requests for off-label information from physicians. Parke-Davis trained the medical liaisons to engage wrongfully in full-scale promotion of Neurontin's off-label uses, with the use of non-scientific, anecdotal information designed to convince physicians that off-label usage of Neurontin was safe and effective. In effect, Defendants used their medical liaisons as a surrogate sales force to solicit physicians regarding off-label uses. Indeed, medical liaisons were selected and promoted based on their ability to sell and sales training was encouraged.

25. Parke-Davis knew this use of medical liaisons was inappropriate. High level personnel employed by Parke-Davis acknowledged that the use of medical liaisons was a thinly disguised method of violating the FDA's policies concerning off-label promotion.

26. On April 16, 1996, at a training session for medical liaisons, Parke-Davis' in-house lawyers stopped the video taping of a medical liaison training session to advise the liaisons that notwithstanding formal policies to the contrary, liaisons were permitted to cold-call physicians as long as they had executed request forms (forms that supposedly verified that the

physician had initiated the meeting) at the end of the call. Moreover, the liaisons were informed that the request forms could be filled out by Parke-Davis' sales representatives instead of the doctors. Company lawyers also informed the liaisons during training sessions that there was no need to present balanced information to the customers, and that liaisons should always remember that sales were necessary in order to keep the company profitable. The liaisons were also informed by the lawyers, off camera, that there really was no definition of "solicitation" and that there were methods to induce the physicians to inquire about off-label uses. The lawyers also warned the liaisons that under no circumstances should any information about off-label uses be put in writing.

27. Medical liaisons were instructed in the clearest possible terms that they were to market and sell Neurontin for its off-label uses. During a teleconference on May 24, 1996, John Ford, a senior marketing executive at Parke-Davis' Morris Plains headquarters, directly informed the medical liaisons that Neurontin should be marketed as a monotherapy, and for pain, bipolar disease, and other psychiatric uses, all of which were off-label. At another meeting with the medical liaisons, Ford was even blunter about "where the money is" and the Company's lack of concern about "that safety crap":

> I want you out there every day selling Neurontin. Look this isn't just me, it's come down from Morris Plains that Neurontin is more profitable.... We all know Neurontin's not growing adjunctive therapy, besides that is not where the money is. Pain management, now that's money. Monotherapy, that's money. We don't want to share these patients with everybody, we want them on Neurontin only. We want their whole drug budget, not a quarter, not half, the whole thing.... We can't wait for them to ask, we need to get out there and tell them up front.... That's where we need to be holding their hand and whispering in their ear Neurontin for pain, Neurontin for monotherapy, Neurontin for bipolar, Neurontin for

> everything.... I don't want to see a single patient coming off Neurontin until they have been up to at least 4800mg/day. I don't want to hear that safety crap either, have you tried Neurontin, every one of you should take one just to see there is nothing, it's a great drug.

28. Thus, the medical liaisons were trained to cold call physicians and sell them on the medical safety and necessity of Neurontin for off-label uses. Key aspects of this selling were misrepresentations. The first thing to be misrepresented was usually the status of the medical liaisons. With the full approval of Defendants' marketing officials, including John Ford, Phil Magistro and John Krukar, medical liaisons were routinely introduced as specialists in the specific drug they were presenting at a particular meeting. Thus, medical liaisons would be presented as experts in anti-epileptic drugs and shortly thereafter as an expert in cardiac medication. Medical liaisons also were encouraged to represent themselves as medical researchers, even though they neither conducted medical research nor analyzed medical research performed by others. It was not uncommon for medical liaisons to be introduced as physicians, even though they had no such qualifications. Sales personnel were instructed to introduce medical liaisons as scientific employees who were given momentary leave of their academic duties to make an individual presentation to the physician. The fact that the liaisons were part of Defendants' standard marketing detail was intentionally hidden.

29. When questions arose concerning the availability of health insurance reimbursement for prescriptions for off-label uses of Neurontin, medical liaisons were instructed by Parke-Davis executives to coach doctors on how to conceal the off-label nature of the prescription.

30. Defendants took numerous actions to conceal their activities from the FDA and the public, including shredding documents, falsifying documents and encouraging medical liaisons to conduct their marketing activities without leaving a "paper trail" that might be discovered.

B. Defendants' Misrepresented the Scientific Information, and Hence the Medical Efficacy, Concerning Off-Label Uses of Neurontin

31. The following misrepresentations relating to scientific informational support for off-label usage of Neurontin were routinely made to physicians in the Northeast and other customer business units with the knowledge and consent of persons such as Phil Magistro, John Krukar, and other of Defendants' marketing personnel.

(a) *Bipolar Disorder*. Medical liaisons informed psychiatrists that early results from clinical trials evaluating Neurontin for the treatment of bipolar disorder indicated a 90% response rate when Neurontin was started at 900mg/day dosage and increased to a dosage of 4800mg/day. No such results existed. Nor was any type of clinical trial being conducted other than a pilot study. There were no clinical trials or studies indicating that Neurontin was safe or effective up to 4800mg/day. Indeed, Defendants were in possession of clinical trial evidence showing that there was no dose response difference between patients who received 600 mg, 1200 mg and 2400mg/day. Any data relating to the use of Neurontin for bipolar disorder was strictly anecdotal and of nominal scientific value. Indeed, most of the published reports on this topic had been written and commercially sponsored by Parke-Davis – a fact not disclosed to physicians. Medical liaisons also were trained to inform psychiatrists that there were no reports of adverse

effects for Neurontin when used for psychiatric purposes despite the fact that Parke-Davis personnel had received such adverse reports.

(b) *Peripheral Neuropathy, Diabetic Neuropathy, and Other Pain Syndromes.* Medical liaisons were trained and instructed to report that "leaks" from clinical trials demonstrated that Neurontin was highly effective in the treatment of various pain syndromes and that a 90% response rate in the treatment of pain was being reported. No such body of evidence existed. Nor was there any legitimate pool of data from which a response rate, much less a 90% response rate, could be calculated. Medical liaisons were trained to claim support for these findings as a result of inside information about clinical trials where no such information existed. The only support for these claims was anecdotal evidence of nominal scientific value. As discussed in more detail below, many of the published case reports were created and/or sponsored by Parke-Davis in articles in which Parke-Davis' involvement and financing was frequently hidden.

(c) *Epilepsy Monotherapy.* Despite the fact that studies had found Neurontin to be safe and effective only as adjunctive therapy, medical liaisons were strongly encouraged to push neurologists to prescribe Neurontin as the sole medication to treat epilepsy and to inform neurologists falsely that substantial evidence supported Parke-Davis' claim that Neurontin was effective as monotherapy. In fact, Parke-Davis knew that clinical trials regarding Neurontin's efficacy as a monotherapy were inconclusive. One of Parke-Davis' clinical trials, 945-82, demonstrated that Neurontin was not an effective monotherapy agent and that the vast majority of epilepsy patients in the study taking Neurontin were unable to continue with Neurontin alone. The same study showed no effective difference between administration of Neurontin at 600, 1200

or 2400mg/day. Notwithstanding this data, Parke-Davis continued to claim that physicians should use Neurontin at substantially higher doses than indicated by the labeling. Indeed, although medical liaisons routinely claimed Neurontin to be effective as monotherapy, in 1997, the FDA refused to find Neurontin to be a safe and effective monotherapy.

(d) *Reflex Sympathetic Dystrophy ("RSD")*. Medical liaisons informed physicians that extensive evidence demonstrated the efficacy of Neurontin in the treatment of RSD. The only such evidence that existed was anecdotal reports of nominal scientific value. Medical liaisons were trained to refer to case reports, most of which had been created or sponsored by Defendants as "studies."

(e) *Attention Deficit Disorder ("ADD")*. Medical liaisons were instructed to inform pediatricians that Neurontin was effective for the treatment of ADD. No data, other than occasional anecdotal evidence, supported this claim. Nonetheless, the medical liaisons were trained to report that a large number of physicians had success treating ADD with Neurontin, when no such case reports existed.

(f) *Restless Leg Syndrome ("RLS")*. RLS was another condition where Defendants' medical liaisons were trained to refer to a growing body of data relating to the condition, when no such scientific data existed. The only reports were anecdotal, most of which had been created and/or sponsored by Parke-Davis.

(g) *Trigeminal Neuralgia*. Although medical liaisons represented that Neurontin could treat Trigeminal Neuralgia, no scientific data supported this claim with the exception of occasional anecdotal reports. No data demonstrated that Neurontin was as effective as currently available pain killers, most of which were comparatively inexpensive.

(h) *Essential Tremor Periodic Limb Movement Disorder ("ETPLMD").* Medical liaisons were trained to allege that Neurontin was effective in the treatment of this condition. No scientific data supported such claims with the exception of anecdotal reports of nominal scientific value.

(i) *Migraine.* Claims that Neurontin was effective in the treatment of migraine headaches were made by the medical liaisons and were supposedly based on early results from clinical trials. Although pilot studies were suggested and undertaken, no early results of clinical trials existed to support these claims. Once again, any data relating to treatment of migraines was purely anecdotal and of nominal scientific value. Most of the case reports were either created or sponsored by Parke-Davis.

(j) *Drug and Alcohol Withdrawal Seizures.* Medical liaisons suggested that Neurontin be used in the treatment of drug and alcohol withdrawals despite the lack of any data supporting Neurontin as an effective treatment for these conditions.

32. Defendants knew these misrepresentations to physicians would cause physicians to provide inaccurate and untruthful medical advice to their patients regarding the medical safety and efficacy of Neurontin to treat off-label conditions. Nonetheless, the representations stated above were routinely made to physicians by Parke-Davis' trained employees. Plaintiff believes, however, that such misrepresentations were made to physicians by Michael Davies, Joseph McFarland, Phil Magistro, Lisa Kellett, Joseph Dymkowski, Daryl Moy, Richard Grady, Ken Lawler and others. Medical liaisons were trained to deliver the misrepresentations described above as part of Parke-Davis' standard pitch to physicians on off-label uses of Neurontin.

33. Each specialist would have received particularized misrepresentations relating to his or her practice. For example, a physician whose practice focused on epilepsy would have received misrepresentations relating to monotherapy, but would not have received information relating to the treatment of ADD. Regardless of the speciality, unsupported claims of effectiveness for off-label usage was a key portion of medical liaisons' presentations relating to Neurontin.

34. A *qui tam* action has been filed in this Court by Dr. David Franklin, who has alleged that he is a former medical liaison for Parke-Davis. Dr. David Franklin makes the following allegations in support of his *qui tam* action:

- Upon order of the company, and as a result of medical liaison training, Dr. Franklin "deliberately contrived reports to mislead physicians into believing that a body of data existed that demonstrated the effectiveness of Neurontin in the treatment of bipolar disease." In fact, no data existed to support the use of Neurontin for bipolar disease.
- Dr. Franklin was trained and instructed to actively deceive physicians with contrived data, falsified "leaks" from clinical trials, scientifically flawed reports, or "success stories" that stated that Neurontin was highly effective in the treatment of a variety of pain syndromes. No such body of evidence existed.
- Dr. Franklin was instructed to advise physicians that Parke-Davis had developed a large body of data to support the use of Neurontin as

monotherapy. This was an "outright lie" and left patients unknowingly without good seizure control.

- Medical liaisons were instructed to tell physicians that a great deal of data existed supporting the safe use of Neurontin at levels that exceed 4800 mg/day. However, clinical safety data existed at dosing levels of only 1800 mg/day.
- Parke-Davis provided medical liaisons with slides stating that Neurontin was effective for the treatment of ADD, but no data existed to support that claim.

35. A group of Parke-Davis' executives called the "New Products Committee" agreed to have Parke-Davis pay for clinical trials to test Neurontin for a variety of uses, including bipolar disorder, social phobia, migraine and chronic pain, and then publicize the results of those trials through medical journals and medical conventions. The head of this committee was the then-president of Parke-Davis, Tony Wild.

36. Defendants publicized these clinical trial results, without disclosing evidence showing that Neurontin was not effective for these off-label conditions.

C. Defendants Concealed their Role in the Creation and Sponsorship of Publications Promoting Neurontin for Off-Label Markets

37. Misrepresentations by Parke-Davis were not limited to representations made by medical liaisons. Parke-Davis distributed materials to physicians that intentionally misrepresented Parke-Davis' role in their creation and sponsorship. The fact that these articles were authored by ghost-writers who were retained by, and who had financial ties to Parke-Davis,

was intentionally concealed in the articles. For example, an article widely circulated by Parke-Davis concerning the use of Neurontin in the treatment of Restless Leg Syndrome falsely asserted that the authors, Gary A. Mellick and Larry B. Mellick, had not and never would receive financial benefit from anyone with an interest in Neurontin. The Mellick brothers, however, were paid tens of thousands of dollars in compensation for their speaking engagements at Parke-Davis' events.

38. Similarly, Parke-Davis often rewarded doctors for their advocacy of Neurontin by paying them an honorarium for lending their names to scientific articles which were actually prepared and written by third parties retained by Defendants. For example, in 1996, Parke-Davis retained AMM/Adelphie, Ltd. ("AMM") and Medical Education Systems, Inc. ("MES") to prepare at least twenty articles for publication in various neurology and psychiatry journals. These articles were written by non-physician technical writers retained by Parke-Davis and it controlled the content of all of the articles, but yet the authors were deceptively listed as independent physicians.

39. The physician "authors" were paid an honorarium of $1,000 to lend their names to these articles, and also were able to claim publication credit on their curriculum vitae. This even occurred in connection with case histories that purported to describe the "author's" personal treatment of actual patients.

40. Defendants' role in creating, approving and sponsoring the articles was hidden from the public. While the articles might reference that the physician author received an honorarium from an outside firm, the articles did not disclose that Parke-Davis had paid the honorarium or controlled the content of the articles. For example, an article created by MES,

Gabapentin and Lamotrignine: Novel Treatments for Mood and Anxiety Disorders, published in CNS Spectrums noted that "an honorarium was received [by the physician "authors"] from Medical Education Systems for preparation of this article," but never revealed that Parke-Davis' hired MES or that MES personnel, while under contract to Parke-Davis, wrote the article.

41. Parke-Davis used these publications as part of their fraudulent marketing strategy. Defendants misrepresented the articles to physicians as evidence of independent research conducted by persons with no monetary interest in Neurontin in order to induce sales of Neurontin.

42. Parke-Davis also paid gratuities to physicians to use Neurontin for so-called "studies" that lacked scientific value. Payments Parke-Davis made for "studies" included the following:

Funded Project Payment	**Payment**
Statistical Analysis of Patients Treated With Neurontin for Pain	$ 7,000
Reduction of Sympathetically Medicated Pain and Sudomotor Function	$ 7,000
Trial of Neurontin for Distal Symmetric Polyneuropathy Associated with AIDS	$20,000
Neurontin for Neuropathic Pain in Chronic Pain Syndromes	$25,000
Retrospective Analysis of Neurontin Use with Bipolar Disorder Patients	$ 5,000
Retrospective Analysis of Neurontin in the Treatment of Pain	$ 2,000
Retrospective Analysis of Neurontin in the Treatment of Chronic Pain	$ 8,000
Case histories relating to use of Neurontin as an adjuvant analgesic	$ 4,000

43. One particularly large "study" conducted by Parke-Davis served as yet another vehicle to financially reward physicians for prescribing Neurontin. In 1995 and 1996, Parke-Davis conducted an enormous clinical trial known as STEPS. STEPS was a marketing tool designed to induce neurologists to prescribe Neurontin at far higher doses than indicated in the FDA approved labeling. In contrast to authentic clinical studies, which have a limited number of

investigators treating a number of patients qualified for the study, the STEPS protocol called for more than 1,200 "investigators" to enroll only a few patients each. Thus, Parke-Davis could channel payments to physician "investigators." The participating physicians were instructed to titrate their patients to higher than labeled dosages of Neurontin to demonstrate that patients could tolerate high dosages of the drug.

44. Physicians were paid for agreeing to participate in the STEPS study and for every patient they enrolled. At the conclusion of the study, Parke-Davis offered the 1,200 "investigators" additional cash for each patient the doctors kept on Neurontin after the study ended. These participating doctors were thus expressly paid for writing Neurontin prescriptions for their patients.

D. Parke-Davis' Systematic Payments to Doctors for the Purpose of Increasing Neurontin Prescriptions

45. Parke-Davis' marketing strategy used physicians (and Parke-Davis' medical liaisons) to perform the work normally performed by the company's sales force in order to promote Neurontin. Parke-Davis made tens of thousands of payments to physicians for the purpose of having those doctors either recommend the prescription of Neurontin or prescribe Neurontin themselves. A description of the various programs used to make these payments to physicians follows.

(a) Consultants Meetings

46. Physicians were often recruited and paid by Parke-Davis to attend dinners or conferences where the physicians would be encouraged to prescribe Neurontin for non-medically necessary off-label uses. Parke-Davis had some doctors sign sham consulting agreements and

attend the meetings as a paid consultant. These consultants were not required to provide any *bona fide* service in exchange for the money. The payments were solely intended to induce the physicians to prescribe Neurontin.

47. A typical "consultants" meeting was held in Jupiter Beach, Florida for neurologists during the weekend of April 19-21, 1996. The "consultants" selected for this meeting were not chosen on the basis of their consulting skills, but because of their potential to write Neurontin prescriptions. In a memorandum announcing the event to Parke-Davis' personnel, the Neurontin Marketing Team acknowledged that in order to target neurologists with the greatest potential for writing Neurontin prescriptions, sales personnel must select potential attendees from a list of the top prescription writers for anti-epileptic drugs in the Northeast. Only persons who fell within this desirable demographic were invited.

48. Qualifying physicians were given round-trip airfare to Florida (worth $800), two-nights accommodations (worth $340), free meals and entertainment, ground transportation and a "consultant's fee" of $250. The Jupiter Beach consultants meeting included two half days of presentations by Parke-Davis personnel relating to Neurontin, including extensive presentations relating to off-label uses. The presentations were made to appear as if sponsored by an independent company, Proworx. However, all aspects of the presentations were designed, monitored, and approved by Parke-Davis. Its personnel selected the speakers, picked the topics and previewed the content of the presentations. Notwithstanding the FDA's prohibition regarding the provision of promotional materials on off-label uses, Parke-Davis provided each of its "consultants" with written abstracts of the presentations that detailed off-label use of Neurontin.

49. No effort was made to obtain professional advice at Jupiter Beach from the "consultants" Parke-Davis had wined, dined, and entertained during the weekend. A follow-up memorandum to Parke-Davis' marketing officials noted that "the participants were delivered a hard hitting message about Neurontin" and emphasized that the participants were encouraged to use Neurontin at higher doses. More importantly, after the conference, Parke-Davis' personnel generated "trending worksheets" listing the doctors who attended the consultants meeting. These worksheets enabled Parke-Davis to track the Neurontin prescription-writing habits of the attendees before and after the consultants meetings to determine if these doctors wrote more Neurontin prescriptions after the conference. Persuading these heavy prescribers to order more Neurontin for their patients was the sole purpose of the Jupiter Beach junket.

50. The Jupiter Beach function was not unique. Parke-Davis hosted dozens of consultants meetings between late 1995 and 1997 in which the "consultants" received payments and gratuities as well as presentations on off-label uses of Neurontin which were designed to change the physicians' prescription writing habits. Comparable consultants meetings included the following:

Topic	**Location**	**Dates**
Mastering Epilepsy	La Costa Resort, CA	July 20-23, 1995
Mastering Epilepsy	Santa Fe, NM	Nov. 16-19, 1995
Neurontin Consultants Conference	Marco Island, FL	February 2-4, 1996
Pediatric Epilepsy	Hutchinson Island, FL	February 9-11, 1996
Mastering Epilepsy Science	Walt Disney World, FL	February 22-25, 1996
Pediatric Epilepsy	Hutchinson Island, FL	March 8-10, 1996

Mastering Epilepsy	Ritz Carlton, Aspen, CO	April 18-21, 1996
Affective Disorders in Psychiatry	Marco Island, FL	April 20, 1996
Affective Disorder Consultants	Southern Pines, NC	April 27, 1996
Neuropathic Pain Conference	Palm Beach, FL	May 11, 1996
Regional Consultants Conference	Ritz Carlton, Boston, MA	May 10-11, 1996
Epilepsy Management Advisors Meeting	Sheraton Grande Torrey Pines, La Jolla, CA	June 21-23, 1996
Epilepsy Management	Ranch Bernardo, CA	June 28-30, 1996
Use of Anti-Convulsants in Psychiatric Disorders	Short Hills, NJ	Oct. 18-19, 1996
Non-epileptic Uses of Neurontin	Longboat Key, FL	Nov. 6, 1996
Neurological Conditions Conference	Ritz Carlton, Atlanta, GA	Sept. 27-28, 1997

Hundreds, if not thousands, of physicians received financial incentives to attend these events.

51. Many consultants meetings consisted of lavish dinners at local restaurants. The emphasis on these meetings was also on off-label uses, and $200 "honorariums" were paid to the physicians for simply showing up. At none of the events did the consultants provide legitimate consultation to Parke-Davis, but at all of the events, the "consultants" were encouraged to increase their writing of prescriptions for Neurontin.

(b) Medical Education Seminars

52. Another format through which Defendants paid financial incentives to physicians were programs billed as Continuing Medical Education ("CME") seminars. These conferences and seminars were set up to appear as "independent seminars" to qualify for an exception to the FDA's off-label marketing restrictions. Federal regulations, however, require that such seminars

must be truly independent of the drug companies. For example, drug companies may make "unrestricted grants" to fund a seminar, but may not be involved in formulating the content of the presentations, picking the speakers or selecting the attendees. None of these requirements were observed with regard to the CME seminars sponsored by Parke-Davis for the promotion of off-label uses of Neurontin. While Parke-Davis retained third-party organizations, such as Proworx and MES, to present the seminars, Parke-Davis controlled virtually every aspect of these events, and the seminar companies obtained Parke-Davis' approval for all content presented at the seminars. Parke-Davis also paid all expenses, including all the seminar companies' fees.

53. For some seminars, high prescription writing physicians were selected to receive junkets comparable to those Parke-Davis provided to the attendees of the Jupiter Beach consultants meetings. Others were less lavish, but physicians received free tuition, free accommodations, free meals, and cash. Frequently Parke-Davis' CME seminars were accredited by continuing medical education organizations. Thus the physicians taking advantage of Parke-Davis' seminars did not have to pay tuition or spend additional time to fulfill their continuing medical education requirements by attending truly independent medical education programs.

54. Representative CME programs sponsored by Parke-Davis where they paid extensive incentives to attending physicians, included the following:

Seminar	**Location**	**Date**
Merritt-Putnam Epilepsy Postgraduate Course		January 19, 1996
Merritt-Putnam Seminar	Chicago, IL	January 26, 1996
New Frontiers in AntiEpileptic Drug Use	California	Sept.-Oct. 1996

Diabetic Neuropathy	Ritz Carlton, Boston, MA	June 22-24, 1997
Merritt Putnam Symposium	Key Biscayne, FL	September 11, 1997
Merritt Putnam Conference on Monotherapy	Palm Springs, CA	September 19, 1997
Merritt Putnam Conference on Monotherapy	St. Louis, MO	October 3, 1997
Merritt Putnam Symposium	Boston, MA	December 5, 1997

(c) Grants and "Studies"

55. Parke-Davis also made outright payments, in the form of grants, to reward demonstrated Neurontin advocates. Parke-Davis' sales managers identified key doctors who actively prescribed Neurontin or programs which were willing to host Neurontin speakers and encouraged such persons or programs to obtain "educational grants" from Parke-Davis.

56. These grants, and others, were charged to Parke-Davis' Neurontin marketing budget. Each of these grants were made solely because the individual receiving the money was a large Neurontin supporter and/or would host a program where a well known Neurontin supporter would recommend that other physicians increase their prescriptions of Neurontin. Each of these grant awards constituted a reward or kickback for the recipient's advocacy of Neurontin.

57. Parke-Davis' medical liaisons informed leading Neurontin prescribers that significant advocacy for Neurontin would result in the payment of large study grants. These studies did not involve significant work for the physicians. Often times they required little more than the collation and write-up office notes or records. Indeed, Parke-Davis frequently hired technical writers to write the articles for which the "authors" had been given grants.

(d) Speakers Bureau

58. Parke-Davis also formed the Speakers Bureau as a subterfuge to pay kickbacks and gratuities to physicians for prescribing Neurontin, particularly for off-label uses. The Speakers Bureau sponsored teleconferences, dinner meetings, consultants meetings, educational seminars, and other events where the off-label uses of Neurontin were marketed. The speakers at these events were physicians who gave short presentations relating to Neurontin for which they were paid by Defendants anywhere from $250 to $3,000 per event. Many speakers received tens of thousands of dollars annually in exchange for recommending to fellow physicians that Neurontin be prescribed, particularly for off-label uses. The payments greatly exceeded the fair value of the work the physicians performed for Parke-Davis. Plaintiff believe that extensive payments through the Speakers Bureau took place at least from 1995 through 2000.

59. Parke-Davis' marketing personnel, including its medical liaison staff, informed physicians of the lucrative rewards of joining the Neurontin Speakers Bureau. Physicians were informed that if they prescribed enough Neurontin, they, too, could be eligible to receive substantial payments just for describing their clinical experience to peers at events dedicated to promoting Neurontin's off-label uses. Parke-Davis' marketing personnel made it clear, however, that the only way the doctors could receive the cash payments was to prescribe substantial amounts of Neurontin to their patients, preferably for off-label uses.

60. Defendants were aware that these payments did not comply with the American Medical Association's guidelines for payments to physicians. They knew and intended that the payments were made for the express purpose of encouraging the physicians to prescribe Neurontin to their patients.

61. In 1997, in the wake of an investigation by the FDA, Parke-Davis conducted a review of its marketing practices. As a result of that review, Parke-Davis determined that none of the programs described above complied with the federal requirements. Parke-Davis issued guidelines which essentially prohibited each of the programs described above. Nonetheless, Parke-Davis' payments to physicians for the off-label marketing of Neurontin did not cease and the programs continued.

VI. TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

62. Any applicable statutes of limitations have been tolled by Defendants' knowing and active concealment and denial of the facts alleged herein. Plaintiff has been kept in ignorance of vital information essential to the pursuit of these claims, without any fault or lack of diligence on their part. Plaintiff could not reasonably have discovered the fraudulent nature of Defendants' conduct. Accordingly, Defendants are estopped from relying on any statutes of limitations.

FIRST CLAIM FOR RELIEF

Violations of the Consumer Protection Statutes of the 50 States, The District of Columbia and the Commonwealth of Puerto Rico

63. Plaintiff repeats and realleges each of the preceding paragraphs, as if fully set forth herein.

64. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in knowing violation of any and all state consumer protection statutes when Defendants knowingly and intentionally misrepresented the medical safety, efficacy and necessity of Neurontin to treat non-FDA approved uses and caused physicians to submit claims

to Plaintiff misrepresenting or concealing the off-label uses for which Neurontin was being prescribed.

65. Defendants knew that the health insurance policies issued by Plaintiff covered Neurontin (a) only for FDA-approved uses or only for medically necessary uses. Defendants' unfair or deceptive acts or practices were specifically designed to induce Plaintiff to pay for Neurontin for off-label and non-medically necessary uses.

66. Defendants have violated the consumer protection statutes of the fifty states, the District of Columbia and the Commonwealth of Puerto Rico, as follows:

(a) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ala. Code §8-19-1, *et seq.*;

(b) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. §45.50.471, *et seq.*;

(c) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz. Rev. Stat. §44-1522, *et seq.*;

(d) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code §4-88-101, *et seq.*;

(e) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code §17200, *et seq.*;

(f) Defendants have engaged in unfair competition or unfair or deceptive acts or practices or has made false representations in violation of Colo. Rev. Stat. §6-1-105, *et seq.*;

(g) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. §42-110b, *et seq.*;

(h) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code §2511, *et seq.*;

(i) Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of D.C. Code §28-3901, *et seq.*;

(j) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. §501.201, *et seq.*;

(k) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. Stat. §10-1-392, *et seq.*;

(l) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. §480, *et seq.*;

(m) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code §48-601, *et seq.*;

(n) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS §50511, *et seq.*;

(o) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. §24-5-0.5.1, *et seq.*;

(p) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code §714.1 b, *et seq.*;

(q) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. §50-623, *et seq.*;

(r) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. §367.110, *et seq.*;

(s) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. §51:1401, *et seq.*;

(t) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. §207, *et seq.*;

(u) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code §13-101, *et seq.*;

(v) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;

(w) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. §445.901, *et seq.*;

(x) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. §325F.67, *et seq.*;

(y) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Miss. Code Ann. §75-24-1, *et seq.*;

(z) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Mo. Rev. Stat. §407.0 10, *et seq.*;

(aa) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code §30-14-101, *et seq.*;

(bb) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. §59-1601, *et seq.*;

(cc) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. §598.0903, *et seq.*;

(dd) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. §358-A: 1, *et seq.*;

(ee) Defendants have engaged in unfair competition or unfair, unconscionable or deceptive acts or practices in violation of N.J. Stat. Ann. §56:8-1, *et seq.*;

(ff) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. §57-12-1, *et seq.*;

(gg) Defendants have engaged in unfair competition or unfair or deceptive acts or practices m violation of N.Y. Gen. Bus. Law §349 *et seq.*;

(hh) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. §75-1.1, *et seq.*;

(ii) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code §51-15-01, *et seq.*;

(jj) Defendants have engaged in unfair competition or unfair or deceptive acts or practices m violation of Ohio Rev. Stat. §1345.0 1, *et seq.*;

(kk) Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of Okla. Stat. tit. 15 §751, *et seq.*;

(ll) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. §646.605, *et seq.*;

(mm) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. §201-1, *et seq.*;

(nn) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws. §6-13.1-1, *et seq.*;

(oo) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws §39-5-10, *et seq.*;

(pp) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws §37-24-1, *et seq.*;

(qq) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code §47-18-101, *et seq.*;

(rr) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code §17.4 1, *et seq.*;

(ss) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. §13-11-1, *et seq.*;

(tt) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. tit. 9, §2451, *et seq.*;

(uu) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code §59.1-196, *et seq.*;

(vv) Defendants have engaged in unfair competition or unfair, deceptive or fraudulent acts or practices in violation of Wash. Rev. Code. §19.86.010, *et seq.*;

(ww) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of W. Va. Code §46A-6-101, *et seq.*;

(xx) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. §100.20, *et seq.*;

(yy) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. §40-12-100, *et seq.*; and

(zz) Defendants have engaged in unfair competition or unfair or deceptive acts or practice in violation of 23 L.P.R.A. § 1001 *et seq*., the applicable statute for the Commonwealth of Puerto Rico.

67. As a direct and proximate result of Defendants' unfair methods of competition and unfair or deceptive acts or practices, Plaintiff has suffered damages in an amount to be proved at trial by paying for Neurontin to treat conditions for which the drug is not FDA approved and is not medically necessary.

SECOND CLAIM FOR RELIEF

Restitution/Disgorgement for Unjust Enrichment

68. Plaintiff repeats and realleges each of the preceding paragraphs, as if fully set forth herein.

69. Plaintiff has conferred on Defendants' benefits in the form of payments for Neurontin that would not have been made had Defendants not engaged in the wrongful acts and practices alleged herein.

70. Retention of the payments and other benefits by Defendants would be inequitable and unjust in this case because Defendants' deceptive conduct caused Plaintiff to pay for Neurontin when they otherwise would not have had to do so.

71. In fairness, under the equitable doctrine of unjust enrichment, Defendants should be required to disgorge to Plaintiff the revenues or profits Defendants earned from their improper sales of Neurontin to Plaintiff.

VIII. DEMAND FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants, jointly and severally, as follows:

(a) On Plaintiff's First Claim for Relief, an award to Plaintiff of the maximum damages allowable under such statutes;

(b) On Plaintiff's Second Claim for Relief, an award to Plaintiff of disgorgement of all sums improperly received by Defendants;

(c) An award of prejudgment interest in the maximum amount allowable by law;

(d) An award to Plaintiff of its costs and expenses in this litigation and reasonable attorneys' and expert fees and expenses; and

(e) An award to Plaintiff of such other and further relief as may be just and proper under the circumstances.

DEMAND FOR A JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury on all issues so triable.

Dated: November 22, 2004

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